American Red Cross

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December 3, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records. [67 FR 56848-56849, September 5, 2002; Docket # 00D-1539]

Dear Docket Officer:

The American Red Cross (ARC or Red Cross) appreciates this opportunity to provide public comments concerning the Food and Drug Administration's (FDA or Agency) draft "Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures; Maintenance of Electronic Records." (Hereafter, referred to as *The Draft Guidance*).

The Red Cross is committed to the safety of our donors, our patients, and the public we serve. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. The plasma donated by Red Cross' volunteers is recovered from blood and further processed or fractionated into plasma derivatives. Red Cross is also a large supplier of human allograft tissue.

Red Cross has several computer systems that contain electronic records heavily relied upon to process the approximately 6 million units of blood and blood products each year. Red Cross acknowledges that our reliance on electronic records will steadily increase and we are committed to ensuring the integrity and quality of our data.

The Red Cross fully supports the intent of *The Draft Guidance* to establish controls and safeguards for maintenance of electronic records. While we continue to agree with many of the recommendations given in *The Draft Guidance*, we offer the following comments for your consideration.

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The Red Cross commends the FDA for providing *The Draft Guidance* as a resource for industry to further interpret the regulatory requirements. Overall, FDA allows flexibility of interpretation and use of *The Draft Guidance* by acknowledging concepts, but not specifying rigid or restrictive limitations in how these concepts must be implemented. Red Cross commends FDA's foresight in recognizing the dynamic nature of computer systems.

However, in certain cases, Red Cross believes that *The Draft Guidance* extends beyond the scope of the 21 CFR Part 11 rule. Given the size and complexity of the task to implement the rule's requirements, Red Cross requests that new precedents detailed below be either removed or proposed through the rulemaking process, rather than proposed through Guidance.

Section 5.2- Red Cross recommends that the Agency remove the term "flash memory device" as an example of a factor that might affect the reliability of electronic records during the required retention period.

Red Cross believes that CFR Part 11 regulations apply only to specific electronic records stored on media, such as magnetic disk or tape, and does not apply to electronic records created on flash memory devices. Flash memory devices are not specifically mentioned in 21 CFR Part 11 rule or in subsequent 21 CFR Part 11 Draft Guidances[1] already issued by the Agency because electronic records maintained on such devices are not equivalent to paper records.

Flash memory is a type of constantly-powered non-volatile memory that can be erased and reprogrammed without need for human intervention. Adding flash memory devices as a factor that must be controlled under *The Draft Guidance* is a requirement that extends beyond the rule's requirements and implies a new requirement (e.g., creation of an audit trail for electronic records stored on flash memory devices).

Red Cross believes an audit trail requirement for electronic records stored on flash memory devices is substantially different from the current 21 CFR Part 11 rule and adds a new level of complexity. If the Agency has found flash memory devices to have greater significance than previously thought, the rule itself should be revised. Further, Red Cross believes a justification for highlighting flash memory devices should be included in the rulemaking record.

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[1] Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation [66 FR 48886 September 24, 2001 Docket # 00D-1538]; Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms [66 FR 48886 September 24, 2001 Docket # 00N-1543]; and Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records [67 FR 68674-68675 November 12, 2002 Docket # 00D-1540]

Section 5.5- Red Cross encourages the Agency to revise Section 5.5 by eliminating the requirement for a one-to-one functionality between the source computer system and the destination computer system.

Specifically, Section 5.5 states:

> Accordingly, where you could use computer technologies to search, sort, or manipulate information in an original electronic record, you should be able to use computer technologies to perform the same kinds of processing on information in the maintained electronic records. For example, if you could automatically search for words in the text of an electronic record, sort or find values in a table, or perform calculations in a spreadsheet, you should be able to process information in a like manner [emphasis added] for the electronic record over the entire records retention period.

Red Cross believes that these statements require the destination computer system to have a one-for-one functionality with the source computer system. Assuming that the destination computer system is properly validated, it is reasonable for a firm to migrate electronic records to a destination computer system that might not have all the functions of the source computer system. One example would be where a firm finds there are benefits to electronic record retention and converts a computer system that results in a limited functionality loss. The functionality loss might never have been used in the source computer system because such functions were ineffective for processing. In this case, the destination computer system may represent an improvement by simplifying processing for the user and reducing the potential for user error.

Red Cross recommends that Section 5.5 of *The Draft Guidance* should be revised to be consistent with Section 6.2.1.5 which recognizes unavoidable differences and losses. Specifically, Section 6.2.1.5 allows appropriate evaluation of functionality that is needed versus functionality that not longer serves a useful purpose. Red Cross urges the Agency to revise Section 5.5 to incorporate the following perspective:

> ...the migrated electronic record could still reliably preserve and present information, despite some losses or modifications, provided that differences are appropriately accounted for, and explained in either the migrated record or readily available electronic documentation.

Section 6.2.1.3- Red Cross recommends that the Agency consider revising this section to eliminate the addition of an audit trail during migration.

Section 6.2.1.3 states:

> For example, section 11.10 (e) of part 11 requires that audit trails record all operator entries and actions that create, modify or delete electronic records. Where a migration, in effect, creates a new electronic record (by

> transforming the old electronic record) then, per section 11.10(e), the audit trail for the migrated electronic record would have to cover this creation. By adding this new creation step to the migrated audit trail carried over from the old electronic record you will help ensure a continuity of electronic record integrity.

Red Cross believes that a specific requirement for updating time-stamped audit trails for data migration is not required in 21 CFR Part 11 rule. Red Cross believes that *Section 6.2, The Electronic Records Migration Approach,* provides sufficient guidance to meet the 21 CFR Part 11 rule's intent.

Section 6.2 states:

> You should document the migration so that you have a traceable history of what systems were used throughout the records retention period.

This section's requirement in conjunction with properly validated software and data review procedures should be adequate to ensure that the data has been successfully migrated with no loss of data integrity.

Creating an audit trail during migration may not be needed in every instance. Data migrations for information systems typically involve automated scripts, procedures or software programs that are written expressly for the data migration. These procedures are validated to prove that data migrations perform as intended. During execution of the data migration process, records are reviewed per procedure to ensure a successful migration.

The extra step in creating the audit trail during migration is unnecessary. Creating audit trail entries for each electronic record would virtually duplicate the requirements in Section 6.2 (stated above) and would not improve the integrity of the migrated data. Moreover, the substantial processing time and storage requirements when migrating millions of electronic records will divert attention from meeting more important remediation plan efforts.

The Red Cross appreciates the Agency's efforts to clarify and communicate their expectations regarding 21 CFR Part 11 rule and this opportunity to provide public comments on *The Draft Guidance*. If you have any further questions or require follow-up, please contact Joel C. Harder, Senior Associate, Regulatory Affairs at 703-351-5942 (phone), 703-351-5948 (fax) or HarderJ@usa.redcross.org (e-mail).

Sincerely,

Kathy Waldman
Vice President, Regulatory Compliance and Quality Systems